

July 20, 1998

Office of Special Nutritionals (HFS-450) 9 2 Center for Food Safety and Applied Nutrition Food and Drug Administration 200 "C" Street SW Washington, DC 20204 98 AUG -5 P1:47

Section 403(r)(6) Notification

Dear Sir or Madam:

In accordance with the requirement of section 403(r)(6) of the Federal Food, Drug and Cosmetic Act, **Leiner Health Products** notifies the FDA that it has begun using the following phrase and statement:

Women's Natural Support for Estrogen Balance

Black Cohosh + Soy Isoflavones is a special combination of herbs and nutrients that complement each other in support of female health during the aging process. Black Cohosh + Soy Isoflavones are natural sources of phytoestrogens that may help naturally balance the body's own estrogen levels. Soy Isoflavones may support bone health. Research suggests that as women age they may benefit from Black Cohosh and Soy Isoflavones.

on the following product:

YourLife® Black Cohosh & Soy Isoflavones

Very truly yours,

Leiner Health Products

Gale Bensussen, President

cc: Michael Bradley, Director of Regulatory Affairs William Cochran, Regulatory Affairs Associate

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